

A multicenter randomised study comparing the efficacy of adefovir dipivoxil versus pegylated interferon alpha-2a plus placebo versus adefovir dipivoxil plus peglyated interferon alpha-2a for the treatment of chronic delta hepatitis

Submission date 03/08/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 09/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 02/02/2011	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

3388

Study information

Scientific Title

Acronym

Delta Study

Study objectives

Peg-interferon alpha-2a or adefovir lead to sustained virological response in 20-40% of the cases in chronic delta hepatitis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Adults with chronic delta hepatitis

Interventions

A: Adefovir dipivoxil, 10 mg, orally (po) for 48 weeks
versus

B: Pegylated interferon alpha-2a, 180 µg subcutaneously (sc), plus placebo for 48 weeks
versus

C: Pegylated interferon alpha-2a, 180 µg sc, plus adefovir dipivoxil, 10 mg po for 48 weeks; biopsy at the end of treatment

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Peg-interferon alpha-2a, adefovir dipivoxil

Primary outcome measure

Response rate of normal ALT and HDV RNA negativity at the end of treatment (ETR)

Secondary outcome measures

1. Response rate of normal ALT and HDV RNA negativity at the end of follow-up (EOF)
2. Suppression of hepatitis B virus (HBV) DNA below 1×10^5 copies/ml at ETR and EOF
3. Paired biopsy comparison
4. HBsAg levels, loss of HBsAg and HBs Antibodies at ETR and EOF
5. HBV and HDV specific T cell response
6. Safety (adverse events, vital signs, clinical laboratory parameters)

Overall study start date

01/04/2004

Completion date

01/10/2004

Eligibility

Key inclusion criteria

1. Age >18 years
2. Positive Hepatitis B surface Antigen (HBsAg)
3. Positive anti-hepatitis D virus (HDV) antibodies
4. Positive HDV-Ribonucleic Acid (RNA) by Polymerase Chain Reaction (PCR)
5. Serum alanine aminotransferase (ALT) >upper limit of normal (ULN) but <10 x ULN
6. Liver biopsy demonstrating liver disease consistent with chronic hepatitis
7. Liver imaging for patients with cirrhosis or marked fibrosis to rule out hepatic carcinoma
8. Negative urine or serum pregnancy test
9. Willingness to give written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

69

Key exclusion criteria

1. Antiviral therapy in previous six months
2. Positive tests for hepatitis A virus (HAV) Immunoglobulin M (IgM) antibodies, hepatitis C virus (HCV) RNA or HCV antibodies or Human Immunodeficiency Virus (HIV) antibodies
3. Serum total bilirubin >2 x ULN
4. Decompensated liver disease Child B-C
5. Other reasons for chronic liver disease
6. Haemoglobin <11.5 g/dl for females and <12.5 g/dl for males
7. White blood cell count (WBC) <3000 cells/mm³
8. Serum creatinine >1.5 x ULN
9. Relevant psychiatric diseases
10. Drug or alcohol abuse within one year of entry
11. Other evidence or history of severe illness
12. Thyroid disease poorly controlled
13. Alpha-fetoprotein (AFP) >100 ng/ml

Date of first enrolment

01/04/2004

Date of final enrolment

01/10/2004

Locations**Countries of recruitment**

Germany

Study participating centre

Medizinische Hochschule Hannover

Hannover

Germany

30625

Sponsor information**Organisation**

Hannover Medical School (MHH) (Germany)

Sponsor details

Kompetenznetz Hepatitis (Hep-Net e.V.)
Department for Gastroenterology, Hepatology and Endocrinology
Carl-Neuberg-Str. 1
Hannover
Germany
30625

Sponsor type

University/education

Website

<http://www.kompetenznetz-hepatitis.de>

ROR

<https://ror.org/00f2yqf98>

Funder(s)

Funder type

University/education

Funder Name

Network of competence for hepatitis (Kompetenznetz Hepatitis [Hep-Net e.V.]), c/o Hannover Medical School (Medizinische Hochschule Hannover [MHH]) (Germany)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/01/2011		Yes	No